

K012601

FEB 06 2002



510(k) Summary

Submitter's name and Address: ClearMedical, Inc.
1776 - 136th Place NE
Bellevue, WA 98005
Ph (425) 401-1414
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FDA Registration Number: 3017110

Contact Person: Richard Radford
Director of Research and Product Development

Date Summary Prepared: August 8, 2001

Trade or Proprietary Name: ClearMedical/Aircast VenaFlow Cuffs (3010, 3012, 3015, and 3016)

Common Name: VenaFlow Cuffs

Classification Name: Sleeve, Limb, Compressible (per 21 CFR section 870.5800)/JOW

Equivalent Device

The ClearMedical/Aircast reprocessed VenaFlow Cuffs are substantially equivalent to the Aircast VenaFlow Cuffs (3010, 3012, 3015, and 3016). This determination has been reached based on an evaluation and analysis of the predicate device's technical and promotional labeling and specific bench testing. For all established indicators of substantial equivalence, the ClearMedical devices demonstrated equality in safety and performance.

Device Description:

The ClearMedical/Aircast VenaFlow Cuffs are an accessory device to a VenaFlow System which is used for the prevention of deep vein thrombosis. The VenaFlow Cuff is designed with two inflatable bladders that fill with air to provide compression to the legs and feet. A connector tubing system attaches the Cuff to the pump system.

CLEARMEDICAL, INC.

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510(k) Summary (Cont'd)

The VenaFlow Cuffs are latex-free, made of a polyester-cotton fabric. They are designed with velcro hook straps, a proximal and distal bladder and polyethylene tubing with polypropylene luer-lock connectors.

Intended Use:

The ClearMedical/Aircast VenaFlow Cuffs are intended as a single patient use accessory to an Aircast VenaFlow system 30A, 30AXL, or 30AXXL pump. The role of the VenaFlow system is to reduce the incidence of deep vein thrombosis, reduce pain and swelling after injury and surgery, and increase arterial blood flow. The VenaFlow Cuffs are used in conjunction with the VenaFlow pump for non-ambulatory patients in a hospital environment.

Technological Characteristics of ClearMedical and Predicate Devices:

The predicate device and the ClearMedical/Aircast VenaFlow Cuffs contain bladders that inflate with air to control circulation of a designated limb. Attached to the Cuffs are connector tubing systems that connect to the VenaFlow pump. In form, the predicate device and the ClearMedical reprocessed VenaFlow Cuffs are substantially equivalent.

Technological indicators of substantial equivalence were identified and included infection control, fit/attachment, bladder function, velcro adhesion and connector function.

The predicate device is delivered to the customer without being labeled either "non-sterile" or "sterile" whereas the ClearMedical/Aircast VenaFlow Cuffs are delivered to the customer labeled "High Level-Disinfected." ClearMedical's infection control methods meet or exceed the CDC and APIC standards for this class of device.

Summary of ClearMedical/Aircast VenaFlow Cuff Performance:

Based on an assessment of bench tests and non-clinical performance data, we believe that in all relevant safety and performance indicators the ClearMedical/Aircast VenaFlow Cuffs demonstrates substantial equivalence to the predicate devices, the Aircast VenaFlow Cuffs.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Richard Radford
Director of Research and Product Development
ClearMedical, Inc.
1776 136th Place NE
Belluvue, WA 98005-2328

Re: K012601
Trade Name: ClearMedical/Aircast VenaFlow Cuffs
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II (two)
Product Code: JOW
Dated: January 16, 2002
Received: January 17, 2002

Dear Mr. Radford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

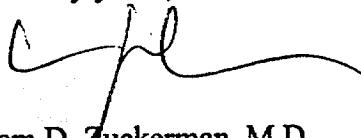
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(K) NUMBER (IF KNOWN): K012601

DEVICE NAME: ClearMedical/Aircast VenaFlow Cuffs

Part Numbers: 3010, 3012, 3015, 3016

INDICATIONS FOR USE:

To reduce the incidence of deep vein thrombosis, reduce pain and swelling after injury or surgery and increase arterial blood flow.

(Please do not write below this line—continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012601

✓
Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use